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In the
Supreme Court of the United States

AMERICAN HOME PRODUCTS CORP. d/b/a/ WYETH, *et al.*,

Petitioners,

v.

MARCELO A. FERRARI, *et al.*,

Respondents.

On Petition for Writ of Certiorari to the Supreme Court of Georgia

BRIEF AMICUS CURIAE OF PACIFIC LEGAL FOUNDATION IN SUPPORT OF PETITIONERS

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QUESTION PRESENTED

In the 1980s, the costs and risks of product liability litigation drove several vaccine manufacturers out of the market, causing shortages of vaccines essential to public health programs. Congress averted a public health crisis by enacting the National Childhood Vaccine Injury Act of 1986. The Act shielded vaccine manufacturers from categories of tort litigation, directed federal agencies to develop safer childhood vaccines, and established a Vaccine Court to administer a no-fault remedy for vaccine-related injuries. The Act's express preemption provision states that "[n]o vaccine manufacturer shall be liable in a civil action" if the injury "resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings." 42 U.S.C. § 300aa-22(b)(1).

Does the Vaccine Act expressly preempt a state-law claim against a vaccine manufacturer based on an allegation that the vaccine-related injury could have been avoided by a vaccine design allegedly safer than the one approved by the United States Food and Drug Administration for use nationwide?

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IDENTITY AND INTEREST OF AMICUS CURIAE

Pacific Legal Foundation (PLF) respectfully submits this brief amicus curiae in support of the Petitioners.[1]

PLF was founded more than 35 years ago and is widely recognized as the largest and most experienced nonprofit legal foundation of its kind. PLF litigates matters affecting the public interest at all levels of state and federal courts and represents the views of thousands of supporters nationwide. In furtherance of PLF's continuing mission to defend individual and economic liberties, the Foundation created its Free Enterprise Project. Through that project, the Foundation seeks to protect the free enterprise system from abusive regulation, the unwarranted expansion of claims and remedies in state civil justice systems, and barriers to the freedom of contract. To that end, PLF participated as Amicus Curiae in this case in the Georgia Supreme Court. *Am. Home Prod. Corp. v. Ferrari*, 668 S.E.2d 236 (Ga. 2008). PLF also participated in several cases before this Court and others on matters affecting the public interest, including issues of preemption and the impact of

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[1] Pursuant to this Court's Rule 37.2(a), all parties have consented to the filing of this brief. Counsel of record for all parties received notice at least 10 days prior to the due date of the Amicus Curiae's intention to file this brief. Letters evidencing such consent have been filed with the Clerk of the Court.

Pursuant to Rule 37.6, Amicus Curiae affirms that no counsel for any party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than Amicus Curiae, its members, or its counsel made a monetary contribution to its preparation or submission.

burdensome state regulations on America's economic vitality. *See, e.g., Pharm. Research and Mfrs. of Am. v. Walsh*, 538 U.S. 644 (2003), *Preston v. Ferrer*, 128 S. Ct. 978 (2008), and *Bank of Am. v. City and County of San Francisco*, 309 F.3d 551 (9th Cir. 2002). PLF attorneys also have published on the public policies supporting tort reform. *See, e.g.*, Deborah J. La Fetra, *Freedom, Responsibility, and Risk: Fundamental Principles Supporting Tort Reform*, 36 Ind. L. Rev. 645 (2003). PLF believes its public policy experience will assist this Court in its consideration of the petition.

REASONS FOR GRANTING THE WRIT

I

RESTORING THE INTEGRITY OF THE VACCINE ACT IS A MATTER OF EXCEPTIONAL, NATIONWIDE IMPORTANCE

The Vaccine Act was enacted in response to a public health emergency of severe vaccine shortages in the mid-1980s due to pharmaceutical companies reacting to threats of extraordinary litigation costs from alleged vaccine-related injuries by withdrawing from the market, leaving children vulnerable to disease. To revitalize the shrinking vaccine market while efficiently compensating the victims of vaccines' rare but inevitable side effects, Congress designed a national statutory scheme to prevent co-regulation of the vaccine market via state tort law. As an alternative to the traditional state tort system, the Vaccine Act provides a federal no-fault compensation program in which people injured by vaccines obtain quick and decisive compensation in exchange for manufacturers' immunity from state tort claims.

If plaintiffs reject the Vaccine Court's decision, the statute expressly restricts the types of state-law claims that the plaintiffs can pursue in state court, primarily by declaring that all federally approved vaccines are unavoidably unsafe, and leaving to the Food and Drug Administration the task of determining which vaccines were nonetheless safe enough to go on the market. 42 U.S.C. § 300aa-22(b)(1). Consistent with the purpose of the Act to reduce the threat of litigation against vaccine manufacturers, Congress used this language apparently to preclude ad hoc jury determinations on the question of safe design. However, by employing a strained reading of legislative history and ignoring the fundamental impetus to reduce lawsuits that drove enactment of the Vaccine Act in the first place, the Georgia Supreme Court subverts the fundamental purpose of the Vaccine Act, putting the nation at risk for reduced availability of vaccines and consequent exposure to preventable diseases. This decision stands in direct conflict with the Third Circuit's decision in *Bruesewitz v. Wyeth Inc.*, 2009 WL 792468, *12, *19 (3d. Cir. 2009) (finding the "Ferrari Court's construction is contrary to the structure of the Act" and holding that "design defect claims are expressly preempted by the Vaccine Act.").

A. The Vaccine Act Was Enacted in an Era of Litigation Crisis

Vaccines are undisputedly an important public health measure that create tremendous benefits to American citizens. However, these benefits were threatened by a litigation crisis that could have crippled the vaccine industry. In response, Congress enacted the Vaccine Act to protect the nation's vaccine

supply and to ensure quick and decisive compensation for vaccine-related injuries.

Vaccines are considered by doctors and public health experts as the "'single most effective [means of] health prevention,'" due to their overwhelming success in reducing the incidence of communicable diseases. Elizabeth A. Breen, *A One Shot Deal: The National Childhood Vaccine Injury Act*, 41 Wm. & Mary L. Rev. 309, 311-12 (1999) (citation omitted). At the turn of the twentieth century, infectious disease proved to be among the greatest health risks threatening the American population. *Id.* (citing H.R. Rep. 99-908 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6345) ("Vaccination of children against deadly, disabling, but preventable infectious diseases has been one of the most spectacularly effective public health initiatives this country has ever undertaken."). In the "fundamentally prevaccine era," for the week ending June 8, 1946, health departments reported 161 cases of polio, 229 cases of diphtheria, 1,886 cases of pertussis, and 25,041 cases of measles. United States Center for Disease Control and Prevention, *Historical Perspectives Notifiable Disease Surveillance and Notifiable Disease Statistics–United States, June 1946 and June 1996*, 45 Morbidity & Mortality Wkly. Rep. 530-36 (June 28, 1996) (*Historical Perspectives*).[2] In stark contrast, after vaccines were made readily available to the public, the Center for Disease Control reported "a cumulative total of no confirmed cases of polio, one case of diphtheria, 1419 cases of pertussis,

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[2] *Available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/00042744.htm (last visited Mar. 16, 2009).

and 263 cases of measles have been reported for 1996." *Id.*

Recognizing the compelling public health benefits achieved by widespread vaccination, the Supreme Court, in a decision as early as 1905, upheld a local ordinance mandating that each individual receive the smallpox vaccine. *Jacobson v. Massachusetts*, 197 U.S. 11, 35 (1905) ("Since, then, vaccination, as a means of protecting a community against smallpox, finds strong support in the experience of this and other countries, no court, much less a jury, is justified in disregarding the action of the legislature simply because in its or their opinion that particular method was—perhaps, or possibly--not the best either for children or adults."). Emboldened by this ruling, states immediately followed suit to enact mandatory vaccination statutes, and every state today requires children to be immunized before attending public school, and many have immunization laws for private schools as well. Derry Ridgway, *No-Fault Vaccine Insurance: Lessons From the National Vaccine Injury Compensation Program*, 24 J. Health Pol. Pol'y & L. 59, 60 (1999).

The successes of mandatory widespread vaccinations were immediate and apparent. For example, while there were a total of 337 reported cases of smallpox in 1946, the last documented cases of smallpox in the United States occurred just three years later in 1949. United States Center for Disease Control and Prevention, *Historical Perspectives*, 45 Morbidity & Mortality Wkly. Rep. 530-36. In 1980, the World Health Organization declared that smallpox had been totally eradicated; today the virus is no longer found outside of laboratories and the vaccination is no longer given routinely in the United

States. *Id.* Widespread polio vaccinations were similarly successful. Between 1955 and 1962, physicians and public health agencies administered 400 million doses of the polio vaccine across the United States. Paul A. Offit, *Why Are Pharmaceutical Companies Gradually Abandoning Vaccines?*, 24 Health Affairs 622 (May 25, 2005).[3] As a result, the number of children paralyzed by polio decreased from 15,000 each year to zero. Paul A. Offit, *Lawsuits Won't Stop Pandemics*, Wall St. J., Dec. 1, 2005, at A16.[4]

Vaccines have been the single most powerful force in enhancing the length and quality of life for the vast majority of Americans. "[D]uring the 20th century, the lifespan of Americans increased by 30 years—mostly because of vaccines." *Id.* Vaccines provide an "extremely cost-effective technology for dealing with killer diseases, saving lives, and averting millions of dollars of potential health spending" in the United States. Patricia M. Danzon, *et al.*, *Vaccine Supply: A Cross-National Perspective*, 24 Health Affairs 706 (May 27, 2005).[5] Vaccines have saved countless lives and greatly improved the health of millions.

Although vaccines are evidently beneficial to a vast number of recipients, they may pose harmful side effects to a small number of children, as is true for any pharmaceutical product. Paula Jacobi, *Pharmaceutical*

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[3] *Available at* http://www.medscape.com/viewarticle/504779 (last visited Mar. 16, 2009).

[4] *Available at* http://www.phrma.org/news_room/press_releases/lawsuits_won%27t_stop_pandemics/ (last visited Mar. 16, 2009).

[5] *Available at* http://www.medscape.com/viewarticle/504780 (last visited Mar. 16, 2009).

Tort Liability: A Justifiable Nemesis to Drug Innovation and Access?, 38 J. Marshall L. Rev. 987, 989 (2005). But of all the medical procedures or pharmaceuticals that carry risks to the recipient, vaccines are especially prone to blame for potential adverse side effects because they are widely administered to young children who appear perfectly healthy at the time of their vaccinations. Inevitably, with a steady flow of millions of vaccinations given each year in the United States, cases of alleged vaccine-related injuries began to surface both in the media and in the courts.

One vaccine in particular, the Diphtheria-Pertussis-Tetanus (DPT) vaccine developed in the 1920s, generated sharp public criticism due to highly publicized cases of the alleged injuries that it caused to children. During the 1970s, increasing numbers of injured persons filed "ever larger claims against manufacturers" of vaccines. Ridgway, *No-Fault Vaccine Insurance*, 24 J. Health Pol. Pol'y & L. at 60. A television documentary in 1982, "DPT Vaccine Roulette," featured children who suffered irreparable neurological disabilities after receiving DPT vaccinations.[6] Breen, *A One Shot Deal*, 41 Wm. & Mary L. Rev. at 315. Increased public awareness spawned lawsuits by injured plaintiffs seeking compensation from DPT manufacturers. By the mid-1980s, the courtroom had become a plaintiff-friendly environment through the expansion of tort remedies available, and the prospect of obtaining extravagant jury-awarded punitive damages against vaccine manufacturers.

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[6] These vaccinations were not the same as the DPT vaccinations currently administered.

Between 1980 and 1986, damage claims for more than $3.5 billion were filed against vaccine producers. Ridgway, *No-Fault Vaccine Insurance*, 24 J. Health Pol. Pol'y & L. at 60-61. As the number of liability lawsuits increased, the number of pharmaceutical manufacturers producing life-saving vaccines diminished rapidly. The "exposure to large damage awards provided the economic justification for companies to stop research and production." Jacobi, *Pharmaceutical Tort Liability*, 38 J. Marshall L. Rev. at 989. Vaccine production became too expensive of an endeavor for these manufacturers to maintain. Increased tort liabilities forced the manufacturers to "reallocate 'an ever larger percentage of revenues from vaccine sales to the costs of insurance and of defending against potential liability.'" La Fetra, *Freedom, Responsibility, and Risk*, 36 Ind. L. Rev. at 650 (quoting John K. Iglehart, *Health Policy Report: Compensating Children with Vaccine-Related Injuries*, 316 New Eng. J. Med. 1283, 1286 (1987)). The cost per dose of the DPT vaccine increased from 11 cents in 1982 to $11.40 in 1986, with $8 of this price going toward liability insurance. *Id.*

Even when manufacturers produced vaccines at increasingly higher costs, they were susceptible to unpredictable future liabilities in the form of punitive damages. Juries were empowered to award massive punitive damages against manufacturers even where scientific evidence was inconclusive as to whether the vaccine had actually caused the injury in question. Elissa Levy, *The Health Act's FDA Defense to Punitive Damages: A Gift to Drug Makers or to the Public?*, 74 Fordham L. Rev. 2425, 2431 (2006). In the mid-1980s, a lawsuit against a manufacturer claiming

that the DPT vaccine caused paralysis in a young boy ended with an award of $1.13 million. *Toner for Toner v. Lederle Laboratories*, 779 F.2d 1429, 1430 (9th Cir. 1986). This award was equivalent to more than half of the entire DPT market. Offit, *Abandoning Vaccines?*, 24 Health Affairs at 622. Although it was later determined that there was no scientific basis to support the claim, pharmaceutical companies were forced to reevaluate their businesses, either withdrawing drugs from the market or leaving the market altogether. Levy, *The Health Act's FDA Defense to Punitive Damages*, 74 Fordham L. Rev. at 2431. Increasing tort liabilities "diminish[ed] the incentives of a manufacturer to research, develop and produce vaccines" so that within the 1980s, ten of the thirteen companies producing vaccines for five serious childhood diseases left the market. La Fetra, *Freedom, Responsibility, and Risk*, 36 Ind. L. Rev. at 650. It was in response to this public health crisis of massive vaccine shortages and skyrocketing costs that Congress enacted the Vaccine Act.

B. The Vaccine Act Achieved Twin Purposes of Ensuring Compensation to Victims and Limiting Manufacturer Liability

Burdened by the skyrocketing costs of defending vaccine-related litigation, manufacturers became unwilling to fulfill the nation's diminishing vaccine supply. At the same time, victims of vaccine-related injuries complained about the traditional tort law system's uncertain recoveries and the high cost of litigation required to obtain compensatory remedies for injuries. The Vaccine Act was enacted as an answer to both of these concerns. Kapil Kumar Bhanot, *What*

Defines a Public Health Emergency? An Analysis of the Strategic National Stockpile and the National Childhood Vaccine Injury Act: The Need for Prevention of Nonterror National Medical Emergencies, 21 J. Contemp. Health L. & Pol'y 137, 140-41 (2004). The Vaccine Act contained two components: the first was created to ensure the supply and development of vaccines through the National Vaccine Program, and the second was to compensate vaccine-related injuries swiftly and decisively through the Vaccine Injury Compensation Program. *Id.* at 141. These "twin purposes" balanced the public health benefits of widespread vaccination with the risks of vaccine-related injuries. Widespread vaccinations inevitably result in rare but unavoidable injuries from the inherent risk of vaccine-related side effects. The National Vaccine Injury Compensation Program provides victims of vaccinations immediate compensation on a no-fault basis without having to undergo time-consuming determinations of causation on a case-by-case basis. *Id.* At the same time, the National Vaccine Program protects manufacturers by restricting the ability of injured vaccine recipients to bring civil actions for damages. The no-fault compensation program provided an incentive for manufacturers to produce vaccines by shielding them from the potential costs of liability litigation. *Id.* Witnesses before Congress characterized the Vaccine Program as promoting "advances in biotechnology that could lead to the production of new and improved vaccines." H.R. Rep. 99-908, 1986 U.S.C.C.A.N. 6344, 6349).

Overall, the twin purposes of the Vaccine Act work jointly by "creating a remedial system that tries more

quickly to deliver compensation to victims, while also reducing insurance and litigation costs for manufacturers. *Schafer v. Am. Cyanamid Co.*, 20 F.3d 1, 2 (1st Cir. 1994); *see also Sykes v. Glaxo-SmithKline*, 484 F. Supp. 2d 289, 297 (E.D. Pa. 2007) (The Vaccine Act was enacted "to prevent manufacturers from leaving vaccine production or significantly increasing [its] prices, while at the same time compensat[ing] victims of vaccine-related injuries quickly."). To achieve its purpose of providing immediate recovery to victims of vaccine-related injuries, the Act instituted a no-fault mechanism where vaccine manufacturers are insulated from excessive liability. *Schafer*, 20 F.3d at 4 ("Congress was importantly motivated not only by the desire effectively to compensate side-effect victims, but also by the desire to keep vaccine prices fairly low by reducing compensation costs.") (citing H.R. Rep. 99-908, 1986 U.S.C.C.A.N. at 6345-48).

The twin purposes of the Act work in tandem such that one cannot exist without the other. For this reason, both the immunity for manufacturers and the compensation remedy are bounded. The Act's preemption clause preserves a limited tort remedy against a manufacturer for injuries caused by a vaccine not made according to its FDA-approved formula or that does not provide proper directions and warnings for use. 42 U.S.C. § 300aa-22(b)(1). Likewise, injured victims may not claim compensation under the Vaccine Act while also suing the manufacturers for state tort liabilities arising from their vaccine-related injuries. Levy, *The Health Act's FDA Defense to Punitive Damages*, 74 Fordham L. Rev. at 2431-32 ("The [Vaccine Act] remove[d] vaccine injury claims out of the

tort system and into a Vaccine Claims court, where the complainants' burdens are eased in exchange for a limited compensation of up to $250,000."). Therefore, to achieve its twin purposes, the Vaccine Act preempts state tort liabilities against vaccine manufacturers from those directly injured by that vaccine, so that the manufacturers may continue producing vaccines and vaccine victims may obtain quick and decisive compensation for their injuries.

The Vaccine Act was designed as a national statutory scheme to best achieve the twin purposes of compensating people injured by vaccines and by encouraging further research, development, and distribution of vaccines that benefit the public health. Compensation of victims without the corresponding preemption of state tort claims would subvert congressional intent by altering the fundamental design and function of the Vaccine Act. This Court should grant certiorari to restore the integrity of the Vaccine Act.

II

GEORGIA'S DECISION TO PERMIT VACCINE DESIGN DEFECT CASES IS AN OUTLIER IN CONFLICT WITH EVERY OTHER COURT, BUT NO LESS DANGEROUS FOR ITS ABERRATIONAL STATUS

A. A Single State Can Cause an Enormous Expansion in Tort Liability

The danger to public health caused by the Georgia Supreme Court's decision should not be understated because this is the first of the state supreme courts or federal appellate courts to rule against preemption in

a vaccine design defect case. History offers many examples of a single expansionist state supreme court causing nationwide ripple effects. For example, the California Supreme Court was a trendsetter in various aspects of tort law. "California recognized new remedies for non-pecuniary injuries, loss of consortium, prenatal injuries, punitive damages, medical monitoring, wrongful life and wrongful birth. Plaintiffs also were permitted to recover against co-defendants under the novel theory of concerted action." Michael L. Rustad & Thomas H. Koenig, *Taming the Tort Monster: The American Civil Justice System as a Battleground of Social Theory*, 68 Brook. L. Rev. 1, 45-46 (2002). *See also Summers v. Tice*, 33 Cal. 2d 80 (1948) (announcing concerted action doctrine later incorporated into the Restatement (Second) of Torts § 433B(d) (1965)); *Greenman v. Yuba Power Prod., Inc.*, 59 Cal. 2d 57 (1963) (establishing strict product liability later incorporated in the Restatement (Second) of Torts § 402A (1965)).

Businesses operating in more than one region of the country suffer economic harm when they must structure their activities and manufacture their products in compliance with differing rules of law in multiple circuits and states. A nationwide manufacturer incurs significant economic costs to avoid liability and to maintain uniformity in its operations by acting in accordance with the law of the most restrictive circuit or state. This Court must step in because otherwise, "'the most restrictive court is effectively binding the nation.'" Robert M. Lawless & Dylan Lager Murray, *An Empirical Analysis of Bankruptcy Certiorari*, 62 Mo. L. Rev. 101, 110-11 (1997) (citation omitted). This practical result runs

afoul of the principle that "a State may not impose economic sanctions on violators of its laws with the intent of changing the tortfeasors' lawful conduct in other States." *BMW of North Am., Inc. v. Gore*, 517 U.S. 559, 572 (1996). Thus, this Court should not wait any longer before resolving the important issue in this case. *Cf. Chamber of Commerce of U.S. v. Brown*, 128 S. Ct. 2408 (2008) (finding federal preemption of state law to avoid patchwork of labor regulation among the fifty states); Respondent's Brief in Opposition, 2007 WL 760217, *20 (2007) (certiorari granted to resolve (disputed) split between Ninth Circuit and Second Circuit, despite respondent arguing that percolation was justified because legislation similar to the challenged California law was pending in fifteen other states and that could result in decision in six additional circuit courts); *Rowe v. New Hampshire Motor Transp. Ass'n*, 128 S. Ct. 989 (2008) (finding federal preemption of state transportation law); Reply in Support of Petition, 2006 WL 3667539, *7 (2006) (petitioner acknowledged that "[n]o other case in the land" interpreted the challenged law as broadly as the First Circuit decision for which certiorari was successfully sought).

B. The Vaccine Act Cannot Survive a Patchwork of State Tort Law

A national preemption scheme is necessary because the risk analysis for vaccines employs a "forward-looking" assessment of future liability for conduct before any potential injury occurs. Victor E. Schwartz & Phil Goldberg, *A Prescription for Drug Liability and Regulation*, 58 Okla. L. Rev. 135, 135-36 (2005). FDA's regulation of vaccines is different from those of other federal agencies because the FDA must

employ extremely "'specialized experience in assessing risks and control measures,'" which the traditional "'tort system is ill-equipped to handle.'" *Id.* at 136 (citations omitted). Overall, the FDA "'administers the most comprehensive drug regulatory system in the world,'" whose mission is to "optimize the risk-benefit tradeoff by only allowing drugs on the market if they are reasonably safe for their intended class of consumers." *Id.* at 141 (citation omitted). Prescription drugs undergo a rigorous approval process, where the FDA uses its considerable scientific expertise "to balance carefully the risks and benefits of each prescription drug, to understand the inherent risks, and to determine how to craft warnings for allowing each drug to be used safely and effectively." *Id.* at 141. The requirements for approval under the FDA are so extensive that, at the margin, the FDA's regulations probably "over-deter[]," such that "tort liability provides no additional societal benefits." W. Kip Viscusi, *et al.*, *Deterring Inefficient Pharmaceutical Litigation: An Economic Rationale for the FDA Regulatory Compliance Defense*, 24 Seton Hall L. Rev. 1437, 1478 (1994) (regarding FDA's regulation of pharmaceuticals in general). Only 8% of prospective products submitted to the FDA receive approval and enter the American market. Schwartz, *A Prescription for Drug Liability and Regulations*, 58 Okla. L. Rev. at 142.

With the Vaccine Act, Congress singled out the vaccine market to be specially regulated by the FDA and immunized from "regulation through litigation" in tort cases. A national statutory scheme is necessary in order to prevent courts from "co-regulat[ing]" the pharmaceuticals industry through "case-by-case

analysis" of vaccine-related liability. Levy, *The Health Act's FDA Defense to Punitive Damages*, 74 Fordham L. Rev. at 2435. As with all prescription drugs and pharmaceuticals, vaccines carry an inherent risk of adverse side effects. Breen, *A One Shot Deal*, 41 Wm. & Mary L. Rev. at 313. But vaccines' side effects, in particular, depend largely on the individual recipient, and make them especially unpredictable. *Id.* Because lay juries and judges focus on a specific injury by a sympathetic plaintiff when they impose liability, juries can fail to acknowledge the tremendous benefits vaccines provide as a public health measure. Levy, *The Health Act's FDA Defense to Punitive Damages*, 74 Fordham L. Rev. at 2435, 2449. The FDA, by contrast, conducts a broader risk-benefit analysis that is vital to the survival of the vaccine industry.

A national statutory scheme is necessary to avoid the patchwork of policymaking by individual states in regulating the national vaccine market. Absent federal preemption against the possibility of state tort claims, pharmaceutical companies operating nationwide are subject to differing legal standards because courts throughout the fifty states may answer the same liability questions differently, and "commentators have persuasively argued that the answers to fundamental tort issues change over time within single jurisdictions." Viscusi, *Deterring Inefficient Pharmaceutical Litigation*, 24 Seton Hall L. Rev. at 1477. Consequently, piecemeal legislative reform at the state level will not produce uniform results. *Id.* Such inconsistency and uncertainty over potential liability increases settlement and litigation costs, the very problem the Vaccine Act was intended to avoid. Levy,

The Health Act's FDA Defense to Punitive Damages, 74 Fordham L. Rev. at 2449-50.

In general, the scope of federal preemption is determined by the underlying purpose of the preemption statute, evidenced both by the overall statutory scheme and the background of its enactment. Considered in this context, the Vaccine Act is a national statutory scheme which centralizes the regulatory authority in the FDA. The decision of the Georgia Supreme Court allows its state tort system to subvert the national scheme that Congress created under the Vaccine Act.

CONCLUSION

The Vaccine Act was designed as a national statutory scheme to best achieve the twin purposes of compensating people injured by vaccines and by encouraging further research, development, and distribution of vaccines that benefit the public health. Compensation of victims without the corresponding preemption of state tort claims would subvert congressional intent by altering the fundamental design and function of the Vaccine Act.

The petition for a writ of certiorari should be granted.

DATED: April, 2009.

Respectfully submitted,

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